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Pain Following Single-bundle versus Double-bundle Anterior Cruciate Ligament Reconstruction: A Systematic Review

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Abstract

BACKGROUND: Double-bundle (DB) anterior cruciate ligament reconstruction (ACLR) has been known to result in better functional outcomes, joint stability, and lower revision rates compared to single-bundle (SB) ACLR. However, given the increased invasiveness and damage to the surrounding tissue area, it is proposed that it may be associated with increased pain.

AIM: This review aims to gather all studies and literature that reported pain as an outcome when comparing SB versus DB ACLR.

METHODS: Literature searching was conducted across seven search engines for studies reporting pain as an outcome and comparing SB versus DB ACLR.

RESULTS: Eight studies met the eligibility criteria and were included in the study. Overall, the studies show variable findings regarding pain in DB compared to SB ACLR, with the only statistically significant results from two studies indicating that DB ACLR is associated with more pain than SB ACLR.

CONCLUSION: Based on the limited evidence available, no conclusions can be made regarding the pain experienced between people receiving either procedure. This constitutes a need for additional studies with increased follow-up time periods, larger sample size, and better study design.

Introduction

The most frequently injured ligament in the knee is the anterior cruciate ligament (ACL), with an annual incidence of 68.8/100.000 person years, and represents the single largest problem affecting athletes [1], [2]. The standard approach to the management of knees with ACL is single-bundle (SB) ACL reconstruction (ACLR). However, it is known that SB ACLR is not effective in managing rotational instability and restoring normal anterior laxity [3]. Moreover, various kinetic studies demonstrated a lack of significant improvement on rotatory stability during walking in patients that underwent SB ACLR [4], [5], [6].

Anatomically, the ACL is composed of two functionally distinct bundles, namely the anteromedial (AM) and posterolateral (PL) bundles that shorten with increasing knee flexion and elongate with extension and exhibit reciprocal tensions [7], [8]. The concept of double-bundle (DB) ACLR was hence borne with the idea that restoring the normal anatomy of the ACL with two bundles will result in improved restoration of normal knee biomechanics and rotational stability [9]. Since then, studies comparing the functional outcomes of knees following either SB or DB ACLR have found that knees following DB ACLR have better rotational stability, return to pre-injury level of activity, and significantly better function scores [10], [11], [12].

With regards to pain following ACLRs, it is known that pain can persist long after functional restoration and may hence interfere with a patients' quality of life [13]. Brown *et al*., goes even further to suggest that pain may inhibit function, limit rehabilitation, and consequently delay long-term recovery [14]. To this end, no gold standard exists for the management of post-operative pain following ACLR [15]. From a surgical perspective, DB ACLR is known to be more invasive and involves more damage to tissues compared to its SB counterpart [16], [17]. Hence, surgeons are presented with another challenge postoperatively that may very well offset the superior functional outcomes thought to be associated with DB ACLR in the long term.

To the best of our knowledge, no review to this date addresses the difference in pain experienced between patients receiving SB or DB ACLR. A previous systematic review by Tiamklang *et al*. in 2012 attempted to explore the outcomes of pain in

SB versus DB ACLR groups but only found 1 study at that time which showed no significant difference in the number of study participants that reported pain in the two groups [10]. This current review aims to gather all studies and literature that reported pain as an outcome when comparing SB versus DB ACLR.

Methods

The writing of this systematic review was done in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [18].

Search strategy

A literature search was performed on 13th July 2020 across seven databases (PubMed, CINAHL, EMBASE, Scopus, ProQuest, ScienceDirect, and The Cochrane Library) for clinical studies that compared anterior knee pain as an outcome to SB versus DB ACLR. Search terms used for these databases were:

Pain AND SB AND DB AND (anterior cruciate ligament OR ACL OR anterior cruciate ligament reconstruction OR ACLR).

Article title and abstracts were screened, followed by the full-text analysis of filtered articles based on pre-set eligibility criteria. In addition, we examined the bibliographies of acquired articles and reviewed articles to identify other studies that fit our eligibility criteria.

Eligibility criteria

The studies this review aims to compile are clinical studies that evaluated pain following SB versus DB ACLR, regardless of the study population, post-operative follow-up timeframe, and level of evidence (LOE). Exclusion criteria included case series, case reports, and studies that did not report complete clinical results, reviews, and *in vitro* or animal studies (Table 1).

Table 1: Eligibility criteria

Inclusion criteria	Exclusion criteria
Population: Patients with ACL rupture	Case series
Intervention: SB or DB ACL Reconstruction	Case reports
	Reviews
Comparator: SB or DB ACL Reconstruction	Animal studies
	In vitro studies
Outcome: Post-operative Pain (VAS Score or Incidence of pain)	Studies that did not report complete clinical results

ACL: Anterior cruciate ligament, DB: Double bundle, SB: Single bundle, VAS: Visual analog scale

Data extraction and analysis

The information pooled from each study included: Patient characteristics, surgery-related data, study design, and pain scores. These pain scores were compared, when possible, across different studies to garner conclusions based off a larger sample size.

Critical appraisal

All eligible studies were evaluated using the LOE grading published by the Journal of Bone and Joint Surgery and Modified Coleman Methodology Score (MCMS) for methodological quality of evidence [19], [20]. The MCMS is comprised of two sections, part A which evaluates study characteristics and part B, which assesses outcome criteria and subject selection processes. Studies with a MCMS of below 55 were considered poor, 55–69 fair, 70–84 good, and 85–100 of excellent methodological quality [19]. Finally, risk of bias assessment was done for each study using The Cochrane Collaboration's Tool, adjusted for this review. We awarded low-risk to studies that scored 0–1, moderate-risk for studies that score 2, and high risk for studies that scored 3 or more potential areas of bias [21].

Results

Search results

The results of this review's literature search are summarized in a PRISMA flow diagram (Figure 1). Eight clinical studies were selected for this review.

Study characteristics

From these eight studies, we found 6 prospective cohort studies (Kondo *et al*., Macdonald *et al*., Morey *et al*., Torkaman *et al*., Zaffagnini *et al*., and Zhang *et al*.), 1 randomized controlled trial (Aglietti *et al*.), and 1 retrospective cohort study (Czamara *et al*.) [15], [22], [23], [24], [25], [26], [27], [28]. Six of these studies were performed within the last 10 years, with exceptions being the randomized controlled trial by Aglietti *et al*. and prospective cohort study by Kondo *et al*. [22], [23].

The collated study population in this review consists of a total of 944 subjects, with a mean age comprising of mostly young active adults (where specified) ranging between 24 years and 31 years of age. The youngest and oldest samples in this review are aged 13 years and 57 years old, respectively, both being in the study by Kondo *et al*. [22]. The study population was predominantly male in four studies, with males composing of 60–100% of samples (Aglietti *et al*., Czamara *et al*., Morey *et al*., and Zhang *et al*.), whereas in the remaining studies, the gender distribution was either similar (Kondo *et al*. and Torkaman *et al*.) or unspecified (Macdonald *et al*. and Torkaman *et al*.) (Table 2) [15], [22], [23], [24], [25], [26], [27], [28].

Figure 1: PRISMA flow diagram describing search results

Table 2: Study characteristics

Author, year	Sample size	Mean age (years)	Male (%)	Average follow-up (months)	Lost to follow-up (%)	Outcome	Study design	LOE	MQOE
Torkaman *et al*., 2016 [25]	160	Not Reported (18–40 years)	-	12–24	6.25	Pain	Prospective cohort study	2	75
Morey *et al*., 2015 [24]	40	SB: 28.3 ± 6.08 DB: 26.4 ± 5.93	97.5	48	20	Pain	Prospective cohort study	2	76
Czamara *et al*., 2015 [28]	30	SB: 30.4 ± 11 DB: 28.4 ± 8	100	6	0	Pain	Retrospective cohort study	3	64
Macdonald *et al*., 2013 [15]	129	SB: 28.6 ± 5.8 DB: 24.7 ± 9.8	-	<1	0	VAS	Prospective cohort study	2	74
Zhang *et al*., 2013 [27]	108	Not Reported Median 31b (22–51 years)	60.2	24	13	Pain	Prospective cohort study	2	79
Zaffagnini *et al*., 2011 [26]	79	SB: 26 ± 9.5 DB: 27 ± 9	53.2	96	12%	Pain	Prospective cohort study	2	83
Aglietti *et al*., 2009 [23]	70	SB: 28 ± 12 DB: 28 ± 12	76	4, 12, 24	0	VAS	Randomized controlled trial	1	83
Kondo *et al*., 2008 [22]	328	SB: 25 (13–52) DB: 27 (14–57)	55	12–24	0	Pain	Prospective cohort study	2	84

SB: Single bundle; DB: Double bundle; VAS: Visual analog scale; LOE: Level of evidence; MQOE: Methodological quality of evidence

The study designs across all trials were comparisons between one group receiving SB ACLR and another receiving DB ACLR. In addition, the study by Macdonald *et al*. further classified population groups based on the type of anesthesia received [15].

All included studies evaluated patients with unilateral chronic isolated ACL lesions; however, only one study (Aglietti *et al*.) specified a time interval of >6 weeks as criteria of inclusion [23].

Five studies excluded patients with concomitant injuries to surrounding structures (medial or lateral collateral ligaments and medial or lateral meniscus injuries), whereas the remaining three studies by Aglietti *et al*., Zhang *et al*., and Zaffagnini *et al*. included patients with medial and lateral meniscal as well as collateral ligament injuries [15], [22], [23], [24], [25], [26], [27], [28]. Six of the eight studies utilized hamstring (gracilis or semitendinosus) tendon grafts

for both SB and DB ACLR (Aglietti *et al*., Kondo *et al*., Czamara *et al*., Macdonald *et al*., Morey *et al*., and Torkaman *et al*.) [15], [22], [23], [24], [25], [26], [27], [28]. Zaffagnini *et al*. utilized the hamstring tendon for their DB ACLR procedures and bone-patellar tendon-bone for SB ACLR, whereas Zhang *et al*. adhered to the tibialis anterior allograft [26], [27].

The use of a tourniquet was reported by two studies (Aglietti *et al*. and Torkaman *et al*.) but was not mentioned in the remaining studies. Most of the included studies did not report the duration of operation in either study groups, with only one study reporting the exact mean duration of operation (Kondo *et al*.) and the other mentioning that their DB ACLR group experienced significantly longer operating times (Macdonald *et al*.) [15], [22]. Only two studies reported anesthesia technique used, the study by Mcdonald *et al*., which performed subgroup analyses between these two types of anesthesia, and Torkaman *et al*. which did not [15], [25]. Post-operative pain management strategies were also scarcely reported, with only 2 studies recording it. Macdonald *et al*. utilized three different categories of analgesics and performed further subgroup analyses on their efficacy in reducing post-operative pain, whereas Czamara *et al*. conducted local cryotherapy during the first 5 weeks of post-operative rehabilitation [15], [28]. Post-operative rehabilitation protocols were similar across most studies, varying only in the use of a knee brace. Studies which utilized the knee brace for rehabilitation include: Zhang *et al*., Kondo *et al*., Morey *et al*., and Torkaman *et al*., whereas Aglietti *et al*. and Zaffagnini *et al*. did not employ the use of a brace for rehabilitation [22], [23], [24], [25], [26], [27]. The studies by Czamara *et al*. and Macdonald *et al*. did not elaborate on their use of a brace during rehabilitation [15], [28] (Table 3).

LOE

Most of the studies included in this review were prospective cohort studies and had a satisfactory LOE [2]. We found one randomized controlled trial by Aglietti *et al*. which was the only study with an LOE of 1, and one retrospective cohort study with an LOE of 3 (Table 2) [23].

MQOE

All of the studies except the study by Czamara *et al*. earned a good MCMS rating. The study by Czamara *et al*. earned a fair score due to the small sample size, short follow-up interval, and retrospective study design [28]. No studies were scored poor or excellent (Table 2).

Pain

Pain was measured in various ways and follow-up intervals across this collection of studies. Aglietti *et al*. and Macdonald *et al*. utilized the visual analog scale (VAS) to evaluate pain upon follow-up, whereas the remaining studies simply evaluated the presence of pain as a qualitative variable. Overall, we've found a statistically significant trend towards greater pain in DB ACLR patients during 1 h, 4, 12 and 24 months post-operatively, based on the findings of Aglietti *et al*. and Macdonald *et al*. [15], [23]. Their findings are supported by those of Torkaman *et al*. and Zhang *et al*., albeit not proven to be statistically significant due to lack of reporting [25], [27]. Two studies (Kondo *et al*., Zaffagnini *et al*.) reported data that revealed an inclination towards greater pain in SB ACLR compared to DB; however, these results were calculated to be statistically insignificant. The remaining two studies (Czamara *et al*., Morey *et al*.) reported a similar incidence of pain in both groups SB and DB ACLR, in which Czamara *et al*. found no patients experiencing pain in either group upon 6 months follow-up (Table 4).

Risk of bias

From our assessment, we found that four studies (Czamara *et al*., Macdonald *et al*., Morey *et al*., and Torkaman *et al*.) were at high risk of bias due to lack of randomization, blinding, incomplete outcome data, and unclear allocation concealment. Two studies were regarded as moderate risk (Morey *et al*. and Zhang *et al*.), and two studies were marked as low risk of bias (Aglietti *et al*. and Zaffagnini *et al*.) (Figure 2).

Table 3: Surgery related information

Author, year	Patients with other structural injuries	Graft type	Tourniquet	Duration of operation	Anesthesia techniques	Post-operative pain management	Brace
Torkaman *et al*., 2016 [25]	None	HT	Used	N/A	General and Spinal	N/A	Used
Morey *et al*., 2015 [24]	None	HT	N/A	N/A	N/A	N/A	Used
Czamara, *et al*., 2015 [28]	None	HT	N/A	N/A	N/A	1–5 weeks: Local cryotherapy	N/A
Macdonald *et al*., 2013 [15]	None	HT	N/A	DB significantly longer	Spinal and general	Post-operative: Oral opioids Oral NSAID Acetaminophen	N/A
Zhang *et al*., 2013 [27]	None	AT	N/A	N/A	N/A	N/A	Used
Zaffagnini *et al*., 2011 [26]	MCL, LCL, Meniscus injuries	SB: BPTB DB: HT	N/A	N/A	N/A	N/A	N/A
Aglietti *et al*., 2009 [23]	Meniscus injuries	HT	Used	N/A	N/A	N/A	Not used
Kondo *et al*., 2008 [22]	None	HT	N/A	N/A	SB: 68 ± 16 DB: 78 ± 25 (p=0.0336)	N/A	Used

HT: Hamstring tendon, BPTB: Bone patellar tendon-bone, AT: Anterior tibia, N/A: Information not available in paper

Table 4: Pain across studies

Author, year	Group size	Pain across follow-up periods							
		1 Hr.	2 Wk.	4 Mo.	6 Mo.	12 Mo.	24 Mo.	>48 Mo.	96 Mo.
Torkaman *et al*., 2016 [25]	SB: 75 DB: 85	-	-	-	-	Pain: 57% Pain: 80% NR	-	-	
Morey *et al*., 2015 [24]	SB: 20 DB: 20	-	-	-	-	-	-	Pain: 4 (20%) Pain: 4 (20%) NS	-
Czamara *et al*., 2015 [28]	SB: 15 DB: 15	-	-	-	Pain: 0 Pain: 0 NS	-	-	-	-
Macdonald *et al*., 2013 [15]	SB: 88 DB: 41	VAS: 2 ± 2.2 VAS: 36 ± 29 (p<0.001)	VAS: 24 ± 7.6 VAS: 25 ± 8.6 NS	-	-	-	-	-	-
Zhang *et al*., 2013 [27]	SB: 58 DB 50	-	-	-	-	-	Pain: 1 (1.7%) Pain: 2 (4.0%) NR	-	-
Zaffagnini *et al*., 2010 [26]	SB: 39 DB: 40	-	-	-	-	-	-	Pain: 14 (36%) Pain: 8 (20%) NS	
Aglietti *et al*., 2009 [23]	SB: 35 DB: 35	-	-	VAS: 6.3 ± 2 VAS: 7.5 ± 1.8 (p<0.05)	-	VAS: 6.9 ± 2 VAS: 7.9 ± 1.8 (p<0.04)	VAS: 7.6 ± 2.2 VAS: 8.6 ± 2.2 (p<0.04)	-	-
Kondo *et al*., 2008 [22]	SB: 157 DB: 171	-	-	-	-	Pain: 8 (5.0%) Pain: 5 (2.9%) NS		-	-

SB: Single bundle, DB: Double bundle, Mo: Months, Wk: Weeks, Hr: Hour, NS: Not significant, NR: Not Reported. Aglietti *et al*. used a 0–10 VAS scale, Macdonald *et al*. used a 0–100 VAS scale

Selection bias

Five studies in this review did not perform randomization of study subjects (Czamara *et al*., Kondo *et al*., Macdonald *et al*., Morey *et al*., and Torkaman *et al*.) and are deemed at risk for selection bias [15], [22], [24], [25], [28]. Only the randomized controlled trial by Aglietti *et al*. and two prospective cohort studies performed satisfactory randomization of their study population via computer generated random sequence of numbers (Agliettie *et al*. and Zaffagnini *et al*.) or by manual randomization using sealed envelopes (Zhang *et al*.) [23], [26], [27].

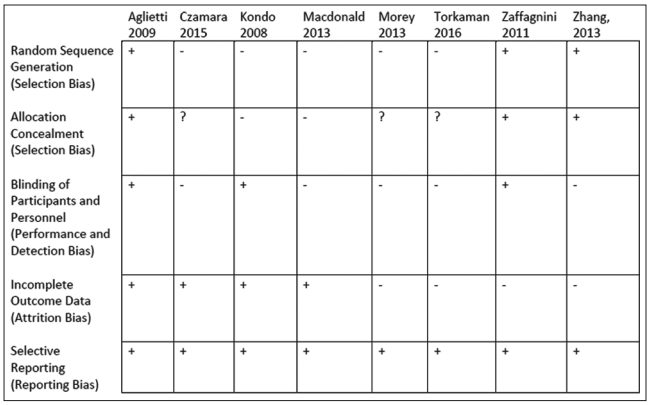

Figure 2: Risk of bias assessment

Only three studies reported adequate allocation concealment in their studies (Aglietti *et al*., Zaffagnini *et al*., and Zhang *et al*.) [23], [26], [27]. Others were inhibited due to their study design; for instance, the study by Macdonald *et al*. performed allocation intraoperatively after evaluating several factors for DB ACLR procedures such as tendon size or footprint areas [15]. In the case of Kondo *et al*.'s study, the operations were performed by one author who was aware that all SB and DB.

ACLR procedures in that hospital were to be included as research subjects, hence foregoing allocation concealment [22]. The remaining studies were unclear about their method of allocation concealment (Czamara *et al*., Morey *et al*., and Torkaman *et al*.) [24], [25], [28].

Performance and detection bias

Three studies performed blinding of outcome evaluation by way of uninformed investigators (Aglietti *et al*., Kondo *et al*., and Zaffagnini *et al*.) [22], [23], [26]. The remaining studies did not perform any form of blinding when evaluating outcome measures and are hence at risk for performance and detection bias).

Attrition bias

While all studies managed to report complete outcome data for each patient, four studies experienced significant losses to follow-up or exclusion of data, putting them at risk for attrition bias (Morey *et al*., Torkaman *et al*., Zaffagnini *et al*., and Zhang *et al*.) [24], [25], [26], [27].

Reporting bias

The studies in this review all reported outcome measures and their corresponding statistics satisfactorily as articulated in their methods section, potentially minimalizing the risk of Reporting Bias.

Discussion

Summary

DB reconstruction of the ACL has been known to yield superior functional outcomes and rotational

stability of the knee. However, little is known regarding the intensity of pain experienced by patients, especially relative to the SB reconstruction. Quantifying pain associated to this procedure is pertinent as pain can potentially stunt rehabilitation progress and limit long-term recovery of knee function.

Pain outcomes following SB versus DB ACLR

The findings from these studies indicate a variety of results regarding which procedure is associated with more pain. However, we found that the only ones that show statistical significance are those that associate DB with greater pain (Aglietti *et al*. at 4, 12, and 24 months and Macdonald *et al*. at 1 h post-operative) [15], [23]. From a surgical standpoint, it is known that the DB reconstruction involves more soft tissue invasion as opposed to the SB procedure. Due to the relatively further posterior position of the PL bundle, the tibial tunnel for the DB procedure typically dissects more of the anteromedial tibia [16]. The DB procedure also involves the drilling of another tunnel on both femur and tibia, which goes through thicker cortical bone and may cause greater drilling damage contributing as a source of pain [17]. Moreover, given that pain is a subjective outcome, patients that underwent DB may be influenced by the interpretation that DB reconstruction is a more extensive operation, representing a psychological aspect to this outcome [15]. In addition, the study by Aglietti *et al*. did not exclude patients with a history of meniscectomy and included 4 patients with a history of meniscectomy in the DB group [23].

This may very well represent a confounding factor as a history of meniscectomy is known to accelerate degenerative joint changes and may account for the higher incidence of pain upon follow-up in their DB group [29].

On the contrary, studies by Kondo *et al*. and Zaffagnini *et al*., show a trend towards a higher incidence of pain in the SB group, albeit statistically insignificant [22], [26]. This may be explained by the better functional outcomes typically associated with patients following DB reconstruction. DB ACLR has been established to provide better rotational stability and hence delays the onset of degenerative changes in the knee joint compared to patients that received SB ACLR [27]. Given the longer-term follow-up periods evaluated by Kondo *et al*. and Zaffagnini *et al*., it is plausible that those in their SB groups were experiencing degenerative knee changes that contributed to the higher incidence of knee pain [22], [26].

Lastly, the remaining studies, most notably those by Czamara *et al*. and Morey *et al*., show similar rates of pain experienced in patients that underwent SB and DB ACLR, suggesting that there is no correlation between pain and the type of procedure employed for ACLR [24], [28].

Surgical-related factors that may contribute to post-operative knee pain

With regards to graft type, several reviews show that HT autographs are superior to BPTB in preventing anterior knee pain [30], [31]. This may suggest a reason behind the higher number of patients experiencing pain in Zaffagnini *et al*.'s SB group, given that their SB group received BPTB grafts and their DB groups were operated on using HT grafts [26].

Tourniquets are not routinely used in ACLR. Its benefits include improved visualization, reduced intra-articular blood loss, and potentially shorter operative time [32], [33], [34]. In contrast, several studies reported that the use of tourniquets following ACLR is associated with neuropathies, muscle weakness and atrophy, increased post-operative pain, and even rare complications such as rhabdomyolysis and thromboembolic events [35], [36], [37], [38], [39]. The effects of tourniquet use on ACLR on post-operative pain are yet to be established due to the existence of conflicting reports that suggest the use of tourniquets in ACLR did not increase post-operative pain [40], [41].

However, based on our findings, one of the only studies to report the use of tourniquets and report pain as a measure of incidence, Torkaman *et al*., reported a much larger percentage of patients that experienced pain compared to other studies that reported pain in a similar manner [25]. Regardless, no conclusions can be made as of this moment as none of the included studies performed subgroup analyses on the effects of tourniquets post ACLR. Hence, the impact of tourniquet use as a confounding factor is still unclear.

When taking into account intraoperative time, several studies have reported that the duration of DB ACLR is significantly longer than SB ACLR and hence the medications administered during surgery would be less effective by post-operative time [22], [42]. These studies help to explain the findings by Macdonald *et al*. where the DB group experienced significantly greater pain at 1 h post-operative, after undergoing a significantly longer intraoperative duration [15]. However, it is not known whether or not the discrepancies in intraoperative time should impact the degree of pain experienced over a time period of 1 year or more.

There are several methods for inducing anesthesia in ACLR. Among these, spinal anesthesia has been associated with the lowest pain scores and longer duration of anesthesia [43]. The methods of inducing anesthesia during surgery were not clearly documented by the studies we included in this review except for Macdonald *et al*. which further divided groups based on either spinal or general anesthesia [15]. Torkaman *et al*. used a combination of spinal and general anesthesia but did not specify how many patients in each group received either method of anesthesia [25]. However, given the relatively longer-term follow-up periods of the studies, we included in this review, the

nature of anesthesia provided intra-operatively may be of insignificant effect.

No gold standard exists for post-operative pain management following ACLR. Several studies have shown that the use of various pain management methods ranging from local infiltration blocks to cryotherapy has proven to be equally efficacious [44], [45]. In terms of pharmacotherapy, the study by Macdonald *et al*. demonstrated that patients receiving oral acetaminophen following ACLR exhibited the lowest pain scores compared to those receiving oral opioids or NSAIDs, indicating that the nature of post-operative analgesics received had a significant effect on post-operative pain [15].

The use of a brace has also been established to reduce pain during rehabilitation and can also pose as a confounding factor when comparing the findings of these studies as not all studies utilized knee bracing in their rehabilitation protocols [46].

Strategies to reduce pain in DB ACLR

For the short term, methods to reduce post-operative pain may very well be determined by the nature of anesthesia. Macdonald *et al*. from their DB ACLR group, those who received spinal anesthesia reported significantly lower pain scores than those that received general anesthesia [15]. These findings are supported by Parvizi *et al*.'s trial of 81 patients that underwent knee arthroscopy found that general anesthesia was associated with higher pain scores as well as shorter duration of algesia [43]. As for other types of nerve blocks, one study by Kassam *et al*. found no significant difference in pain scores between sciatic or femoral nerve blocks in patients that underwent ACLR [47]. However, several studies have shown that a combination of sciatic-femoral nerve blocks is superior to spinal anesthesia or individual femoral nerve blocks in terms of reducing post-operative pain scores [48], [49]. Appropriate post-operative pain management also plays an important role in reducing patient pain following ACLR. Baverel *et al*. recommend a variety of methods, including periarticular local infiltration analgesia, sensory saphenous nerve block, NSAIDs, intravenous corticosteroids, and cryotherapy [45]. In terms of pharmacotherapy, the findings of Macdonald *et al*. have shown us that acetaminophen is more superior than oral opioids or NSAIDs in relieving pain 14 days postoperatively. This may be useful for surgeons looking to reduce post-operative pain following DB ACLR.

Long-term strategies to reduce post-operative pain would require attention to rehabilitation methods. Except for Torkaman *et al*., in our pool of studies, those that implemented the use of knee braces during post-operative rehabilitation reported a low percentage of patients experiencing pain (Kondo *et al*., Macdonald *et al*., and Zhang *et al*.) [15], [22], [27]. Although no statistical analysis was performed, this finding may divulge a potential strategy to reduce post-ACLR knee pain. Brandsson *et al*. affirmed that the use of knee brace post-ACLR was associated with significantly reduced pain and laxity during the early phase of rehabilitation [46].

Quality of evidence

There was a generally high risk of bias across half the studies in this review based on our analysis, this was mainly due to the lack of randomization, allocation concealment, and blinding in four studies. With regards to selection bias, most of these studies did not attempt to reduce it by performing selection bias or allocation concealment. Various circumstances underlie the possibility of randomization; for instance, the study by Yasuda *et al*. elaborates that the concept of a randomized surgical trial is not well received by their Japanese population and is hence not done [17]. Another reason for the lack of randomization may be due to study design, in which certain studies such as the retrospective cohort study by Czamara *et al*. may not be able to perform randomization as the study was only conceived after the surgeries had been done [28].

Only three studies made an effort at randomization using a randomly generated sequence of numbers or envelopes [23], [26], [27]. While double-blinding may not be possible due to ethical issues surrounding patient informed consent, several of these pooled studies have shown us that single-blinding of investigators evaluating outcomes is highly feasible with the right study protocol and can still reduce the risk of performance and detection bias [23], [26].

From a methodological perspective, none of the studies in this review scored an excellent MCMS (>85), with several studies falling short of the benchmark [22], [23], [26]. This was due to several issues common to all studies having one or more of the following: Short-term follow-up (<3 years), inferior study design, and small sample size. The only study that scored a maximum of 5 points for follow-up period was Zaffagnini *et al*., with a follow-up of 6 years, whereas the remaining studies performed to follow-up of <5 years [26]. A cohort study that conducted an 11-year follow-up found that degenerative changes typically accelerate in 5 years post-injury, indicating that a longer observation period is warranted to better detect the onset of degenerative changes in the post-operative knee and how they might contribute to pain later on [50]. With regards to sample size, three studies performed a power analysis to determine and justify their sample sizes (Aglietti *et al*., Kondo *et al*., and Zaffagnini *et al*.) [22], [23], [26]. The remaining studies did not conduct a power analysis and hence were not ascertained to have a sufficiently powered sample size. From a study design standpoint, most of the studies included in this review were prospective cohort studies which are of satisfactory LOE. Moreover, some of these cohort studies (Zaffagnini *et al*. and Zhang

et al.) managed to incorporate randomization, hence improving their study design [26], [27].

Limitations of studies

Studies that included patients with concomitant meniscal or collateral ligament injuries did not perform subgroup analysis to quantify their effects on pain, leading to confounding factors in their outcomes [23], [26], [27]. Only one study reported outcomes of >5 years, indicating a lack of data on the long-term prognosis of pain associated with either type of ACLR [26]. One study also utilized different graft types and fixation devices in the same population group, introducing additional variables [26].

Recommendations for future studies

We would advise future studies to employ similar study designs longer-term follow-ups with a larger sample size. Randomization, allocation concealment, and single blinding of outcome investigators are possible and should be strived for in every study. Studies should also attempt to exclude patients with other structural injuries in the ipsilateral knee or perform subgroup analyses for them to better establish the effects of different types of ACLR on post-operative pain. Finally, we recommend future studies to report operation duration, type of anesthesia used, and post-operative pain management protocols to establish their roles in contributing to pain post-ACLR.

Limitations of review

The findings from this review cannot be generalized to different types of ACLR techniques, graft types, and fixation methods not covered in the studies included in this review. In terms of pain as a subjective outcome, there are many confounding factors that make the standardization of this measure difficult. Psychological factors such as kinesiophobia (fear of moving) and pain catastrophizing have been found to increase the incidence of future knee pain and cannot be quantified to remove its confounding effect [51].

Finally, it should be noted that the MCMS is merely an indicator of methodological quality as it only assesses the quality of reporting not the actual quality of the study [52].

Conclusion

Summary of findings

In summary, based on the current data, we cannot draw any conclusions regarding which procedure is associated with more pain due to the conflicting nature of the evidence available. Given the advantages DB ACLR offers, including increased joint stability, functional outcome, and reduced revision rate due to its anatomically superior makeup, it might still be the superior choice compared to its SB counterpart. However, our findings show that it may very well be associated with significantly increased pain, particularly in patients with concomitant structural injuries. Based on this, the need for future studies with longer-term follow-up, improved study design, and larger sample size is still justified.

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